Summary of Safety and Effectiveness for the Whisper Wear Breast Pump

submitted by
Whisper Wear, Inc.
2221 Newmarket Parkway, Suite 136
Marietta, GA 30067
Phone: (770) 984-0905

Contact Person: Al Weisenborn
Device Trade Name: Whisper Wear Breast Pump
Common Name: Breast Pump
Classification Name: Powered Breast Pump per 21 CFR § 884.5160

Identification of a Legally Marketed Predicate Device

The Whisper Wear, Inc. Breast Pump is substantially equivalent to the Medela Mini Electric® Breastpump, which is legally marketed and distributed by Medela, Inc. pursuant to 510(k) K901344.

Device Description

The Whisper Wear Breast Pump is a self-contained, battery-operated device that is worn under and held in place by everyday clothing. A DC motor imparts motion to a silicone diaphragm that develops a negative pressure that expresses milk from the breast to a collection bag.

Intended Use

The Whisper Wear Powered Breast Pump is intended for use by lactating women to express and collect breast milk.

Summary of Technological Characteristics

Thirteen (13) technological characteristics of the Whisper Wear, Inc. Breast Pump were compared to those of predicate device and found to be equivalent.

Summary of Performance Data

The Whisper Wear, Inc. Breast Pump complies with the following standards, practices, and guidances:

- 10993-1, *Biological Evaluation—Part 1: Guidance on Selection of Tests*
- 10993-5, *Biological Evaluation—Part 5: Tests for Cytotoxicity: In Vitro Methods*

- 10993-10, *Biological Evaluation—Part 10: Tests for irritation and sensitization*
- UL 1431, *Personal Hygiene and Health Care Appliances*
- UL 2601-1, *Medical Electrical Equipment, Part 1: General Requirements for Safety*

The Whisper Wear, Inc. Breast Pump is substantially equivalent to the Medela Mini Electric® Breastpump, which is legally marketed and distributed by Medela, Inc. pursuant to 510(k) K901344. This has been demonstrated through a series of bench tests including vacuum and cycle rate performance.

The tissue contact and milk contact materials used to fabricate the Whisper Wear Breast Pump and Collection Bags have a long history of safe usage. Since the Whisper Wear Breast Pump and Collection Bags meet the requirements of the stated standards and embody technological characteristics essentially identical to the predicate device, we believe the device is safe and effective and performs as well as or better than the predicate device. The Whisper Wear Breast Pump and Collection Bags will be manufactured per specifications and good manufacturing practices that ensure the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 0 2002

Whisper Wear Incorporated
c/o Mr. Al Weisenborn
Certified Quality Engineer
19526 East Lake Drive
MIAMI FL 33015

Re: K022140
Trade /Device Name: Whisper Wear Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: 85 HGX
Dated: July 1, 2002
Received: July 2, 2002

Dear Mr. Weisenborn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Page 1 of 1

510(k) Number (if known): K022140

Device Name: Breast Pump

Indications for Use:

The Whisper Wear Powered Breast Pump is intended for use by lactating women to express and collect breast milk.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use__X__
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

David G. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022140